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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,424	01/22/2001	Sara L. Zaknoen	OC01121K	9553

24265 7590 02/25/2002

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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KENILWORTH, NJ 07033-0530

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/767,424

Applicant(s)

ZAKNOEN, SARA L.

Examiner

Sheela J Huff

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: .

### **DETAILED ACTION**

Claims 1-22 are pending.

#### ***Information Disclosure Statement***

The IDS filed 6/5/01 has been considered and an initialed copy of the PTO-1449 is enclosed.

#### ***Priority***

Applicant has priority to provisional application 60/177624 filed 1/24/00.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declaration states that the provisional application was filed on 1/18/01. The provisional application was filed 1/24/00 not 1/18/01.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/12630 in view of Ragab US 6346524 (priority to 3/30/99) and Kline US 6180096 (which has priority to 3/26/98) or WO 95/13090.

WO 97/12630 discloses the combination therapy of cancer using temozolomide and interferon alpha 2b. The concentration of temozolomide ranges from 50-400 mg/m<sup>2</sup> with a daily dose administered over a 2-10 day period and can be administered in repeated cycles of 28-42 days. The concentration of interferon alpha 2b ranges from 1 million to 25 million IU per m<sup>2</sup>. (see pages 3-5).

The only differences between the instant invention and the reference is the use of PEG<sub>12000</sub>-interferon alpha 2b, the specific concentrations of PEG<sub>12000</sub>-interferon alpha 2b and the formation of a kit.

Ragab discloses a dosing cycle of temozolomide of daily administrations for 5-25 days (at 40-150mg/m<sup>2</sup>/day) followed by a rest period of 4-15 days (abstract).

Kline discloses at PEG stabilizes interferon alpha during lyophilization and specifically exemplifies PEG 12000 and interferon alpha 2b (see entire reference).

WO 95/13090 discloses the formation of long-acting alpha interferon compositions using PEG and specifically discloses the use of using PEG with a MW ranging from 2000-12,500 (see page 6, lines 18-21 and page 2, lines 25+).

Thus, in view of the fact that PEG 12000 stabilizes interferon alpha 2b during lyophilization and that PEG in the range of 2000-12500 creates a long-acting alpha interferon, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to use interferon alpha 2b linked to PEG 12000 to form a more stable, long-acting interferon alpha 2b. The formation of a kit using known components is within the purview of one skilled in the art. Furthermore, the dosing cycle of temozolomide of daily administrations for 5-25 days (at 40-150mg/m<sup>2</sup>/day) followed by a rest period of 4-15 days is obvious in view of Ragab. Further optimization of dosages and dosing regimes is within the purview of one skilled in the art.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on M,Th 5:30 am-2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in cursive script, reading "Sheela J Huff".

Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh  
February 21, 2002